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APR 12 2005

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In re Application of
Krishan L. Taneja
Serial No. : 09/627,796
Filed : 28 July 2000
Attorney Dkt No. : BP9806US-CP2

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144 or 1.181 filed on 03 August 2004, to request withdrawal of the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on July 28 2000 with 45 claims (27 pages).

A requirement for restriction was mailed to applicants on September 21, 2001, requiring the restriction of the 45 claims to one of eighteen inventions under 35 U.S.C. 121. The claims were restricted as follows:

Groups I-V, VII, IX XI-XVI, claims 1-15, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosomes X, Y, 1, 2, 3, 6, 8, 10, 11, 12, 16, 17 and 18, respectively, and methods and kits for detecting, identifying, or quantitating said human chromosome in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group VI, claims 1-16, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 4 and methods and kits for detecting, identifying, or quantitating human chromosome 4 in a sample, classified in class 536, subclass 23.1 and 435, subclass 6,

Group VIII, claims 1-15, 17, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 7 and methods and kits for detecting, identifying, or quantitating human chromosome 7 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group X, claims 1-15, 18, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 9 and methods and kits for detecting, identifying, or quantitating human chromosome 9 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;

Group XVII, claims 1-15, 19, 21-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome 20 and methods and kits for detecting,

identifying, or quantitating human chromosome 20 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6;
Group XVIII, claims 1-15, 20-23 and 29-45, drawn to [peptide] nucleic acid probes directed to human chromosome pair 13/21 and methods and kits for detecting, identifying, or quantitating human chromosome pair 13/21 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
The examiner stated that the reasons for the restriction were based upon the following:

> The inventions are distinct, each from the other because of the following reasons: Each group is directed to [peptide] nucleic acid sequences that identify or detect a different human chromosome. Each of the sequences are structurally and functionally different from each other. That is structurally, the sequences comprise a different sequence(s) of nucleotide bases, thus resulting in unique sequences. Functionally, the sequences are different in that they identify or detect different chromosome...

Applicants' traversal of the above restriction requirement on a number of different bases was not found persuasive by the office.

DISCUSSION

Applicants petition under 37 C.F.R. 1.144 or 1.181, to withdraw the restriction requirement. Applicants complete argument supporting applicants position that the previous restriction requirement be withdrawn, is acknowledged.

With respect to the nature of the invention, the claimed probes are not traditional nucleic acids, they are PNA or Peptide-Nucleic acids and have been claimed as "Non nucleic acid probes." The difference with a PNA is that the backbone is not a traditional sugar-phosphate nucleic acid backbone, but one that has peptide structures. PNA's function like nucleic acids in that they contain a sequence of bases (usually traditional nucleotide bases) (what is termed in the claims as a probing nucleobase sequence) which is responsible for the hybridization of a PNA to DNA. Thus it is the nucleobase sequence that controls the function and specificity of PNAs (see specification page 6, lines 25-29).

Applicants traverse the present restriction requirement as being clearly contrary to the express holding of *In re Weber*. Applicants submit that *In re Weber* holds that:

> It is apparent that 121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be "independent and distinct'. It does not, however, provide a basis to an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis. In re Weber, 580 F.2d 455, 458, 198 U.S.P.Q. 328, __ (CCPA, 1978) We hold that a rejection under 121 violates the basic right of the **applicant to claim his invention as he chooses** (emphasis added). In re Weber, 580 F.2d 455, 459, 198 U.S.P.Q. 328, __(CCPA, 1978)

Applicants thus submit that the legal issue of whether or not the Office may impose a restriction requirement to a single claim has been decided against the Office and that it is well settled that such a requirement violates 35 U.S.C. 112, where the applicant is statutorily entitled to claim his invention as he deems proper, notwithstanding 35 U.S.C. 121. Applicants further submit that this is true whether or not the inventions are determined by the Office to be independent and distinct.

> Applicants' attention is drawn to the MPEP 803.02, which states:
>
> Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The 159 peptide nucleic acid sequences recited in claim 1 of the instant application do not share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility. Probes which bind to a common structure, such as a selected chromosome, are not required to share a common structure. This is the case in the instant application and the Office has separated the probes based on their specific chromosome binding affinity (i.e. binding to chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 or 20, etc...) and thus every invention has been placed within a group.

As each of the 159 independent and distinct peptide nucleic acid sequences listed in claim 1 and thus the claimed PNA probes comprising said sequences do not share a common utility nor a substantial structural feature disclosed as being essential to said utility, it is thus proper for the Office to set forth a restriction requirement within a claim. Further, election of species practice is not required.

Because the embodiments are listed in the alternative, applicants can achieve coverage of the full scope of the claims by the appropriate filing of divisional applications, without the loss of scope of the claimed invention.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

It is noted that the elected group under examination is directed to 7 independent and distinct peptide nucleic acid sequences and said 7 sequences is in the range of 1-10 as per 1192 O.G. 68 (November 19, 1996), Examination of Patent Applications Containing Nucleotide Sequences.

Applicants further note the similar classification (i.e. Class 536, subclass 23.1 and Class 435, subclass) of each Group that the Examiner has argued is a separate invention.

Applicants submit that based upon the similar classification, for purposes of a search, there is no additional burden placed upon the office since the same class and subclass must be searched and no additional Class or subclass must be searched.

Applicants' argument regarding the additional search burden imposed by the examination of all of the claims is acknowledged, however, not found persuasive. The mere similar classification of clearly different inventive subject matter is not a reason for maintaining said subject matter together. This can be seen by the number of clearly different inventions that can be found in the same class and subclass, such as class 536, subclass 23.1, in which any peptide nucleic acid probe would be classified. Additionally each peptide nucleic acid sequence must be searched independently of other peptide nucleic acid sequences in a number of different peptide nucleic acid databases in addition to any class/subclass searches.

Finally applicants take the position that said claims are generic and use proper Markush format.

Applicants' attention is again directed to the MPEP section 803.02 which deals with the treatment of Markush-Type claims which list alternatives having a common core structure and function:

> If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

Clearly this is not the situation in the instant application, as claim 1, the subject of the current petition to withdraw the restriction requirement contains at a minimum 159 independent and distinct peptide nucleic acid sequences.

As discussed above, the 159 peptide nucleic acid sequences listed in claim 1 lack a common structural feature essential to the common utility and therefore election of species practice is not required.

Thus applicants' complete argument supporting applicants position that the previous restriction requirement be withdrawn, is acknowledged, however not found persuasive.

DECISION

For these reasons, the Renewed Petition under 37 C.F.R. 1.144 and 1.181 to request withdrawal of the restriction requirement is **DENIED**.

The application will be forwarded to the examiner to consider the response filed 9/8/2004.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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